REMARKS/ARGUMENTS

In the Final Rejection dated January 25, 2007, the Examiner rejected claims 1-13 and 18 either under 35 U.S.C. §102(e) as allegedly anticipated by, or under 35 U.S.C. §103(a) as allegedly obvious over Kerr, et al. (U.S. Patent Publication No. 2006/0079925). However, Applicant submits herewith a Declaration under 37 CFR §1.131 of Yaron Keidar establishing a date of invention prior to the May 27, 2003 effective date of the Kerr reference. Accordingly, Applicant respectfully requests removal of Kerr as a reference.

The Examiner also rejected claims 14-17 and 19 under 35 U.S.C. §103(a) as allegedly obvious over Kerr in view of either Wallace, et al. (U.S. Patent No. 6,254,628) or Devos, et al. (U.S. Patent No. 6,099,511). However, Kerr is not prior art to the present application as discussed above, and neither Wallace nor Devos disclose the catheters recited in independent claims 1 and 18. Accordingly, independent claims 1 and 18, and all claims dependent therefrom, including claims 14-17 and 19, are allowable over Wallace and Devos.

Claims 1-19 remain pending in this application, with claims 20-22 being withdrawn from consideration. In view of the above remarks, Applicant submits that all of pending claims 1-19 are in condition for allowance. Applicant therefore respectfully requests a timely indication of allowance. However, if there are any remaining issues that can be addressed by telephone, Applicant invites the Examiner to contact Applicant's counsel at the number indicated below.

Respectfully submitted,
CHRISTIE, PARKER & HALE, LLP

By _____
Anne Wang
Reg. No. 36,045
626/795-9900

LES/les

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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

I hereby certify that this correspondence is being deposited with the U.S. Postal Service as first class mail in an envelope addressed to Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on 4/24/07.

Lisa D. Brunk

Appl No.	: 10/618,033	Confirmation No. 4112
Applicant	: Yaron Keidar	
Filed	: July 11, 2003	
Title	: TRANS-SEPTAL SHEATH WITH SPLITTING DILATING NEEDLE AND METHOD FOR ITS USE	
TC/A.U.	: 3731	
Examiner	: Timothy J. Neal	
Docket No.	: 50572/W112	
Customer No.	: 23363	

DECLARATION UNDER 37 C.F.R. § 1.131

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Post Office Box 7068
Pasadena, CA 91109-7068
April 24, 2007

Commissioner:

I, Yaron Keidar, declare and state the following:

1. I am the sole inventor of the subject matter described and claimed in the above identified patent application, filed on July 11, 2003, the entire content of which is hereby expressly incorporated by reference.

2. On or before May 27, 2003, I conceived the invention claimed in this application. I then prepared the attached invention report, generally describing exemplary embodiments of the invention, and submitted that invention report to Biosense Webster, Inc., the assignee of this application. A true and correct copy of the invention report except for the dates which have been redacted, are attached to this Declaration as Exhibit A.

3. I worked diligently with patent attorneys to prepare a non-provisional patent application describing the subject matter set forth in the invention report.

4. Upon receipt of each draft of the non-provisional application, I reviewed the application to ensure that my inventive concepts were adequately described.

5. Non-provisional United States Patent Application No. 10/618,033 was filed on July 11, 2003 in the United States Patent and Trademark Office.

6. I declare that all statements made herein are of my own knowledge, are true, and that all statements made on information and belief are believed to be true. The statements herein are made with the knowledge that willful false statements are punishable by fine, imprisonment, or both, under Title 18, § 1001 of the United States Code, and that such willful statements may jeopardize the validity of this application or any patent issued on this application.

Date: April 19, 2007 By: _____
Yaron Keidar

AW/ldb

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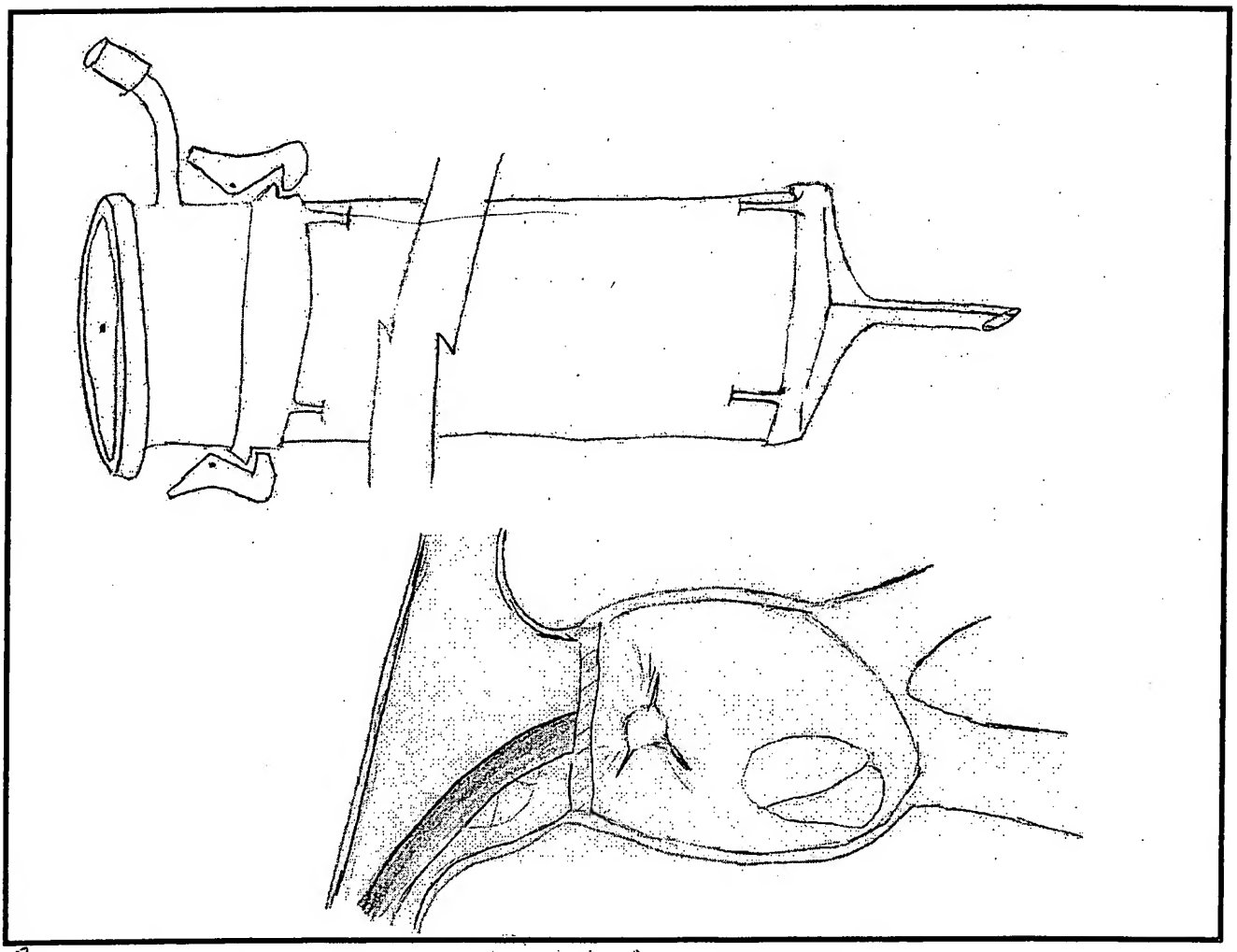
Cordis
a Johnson & Johnson company

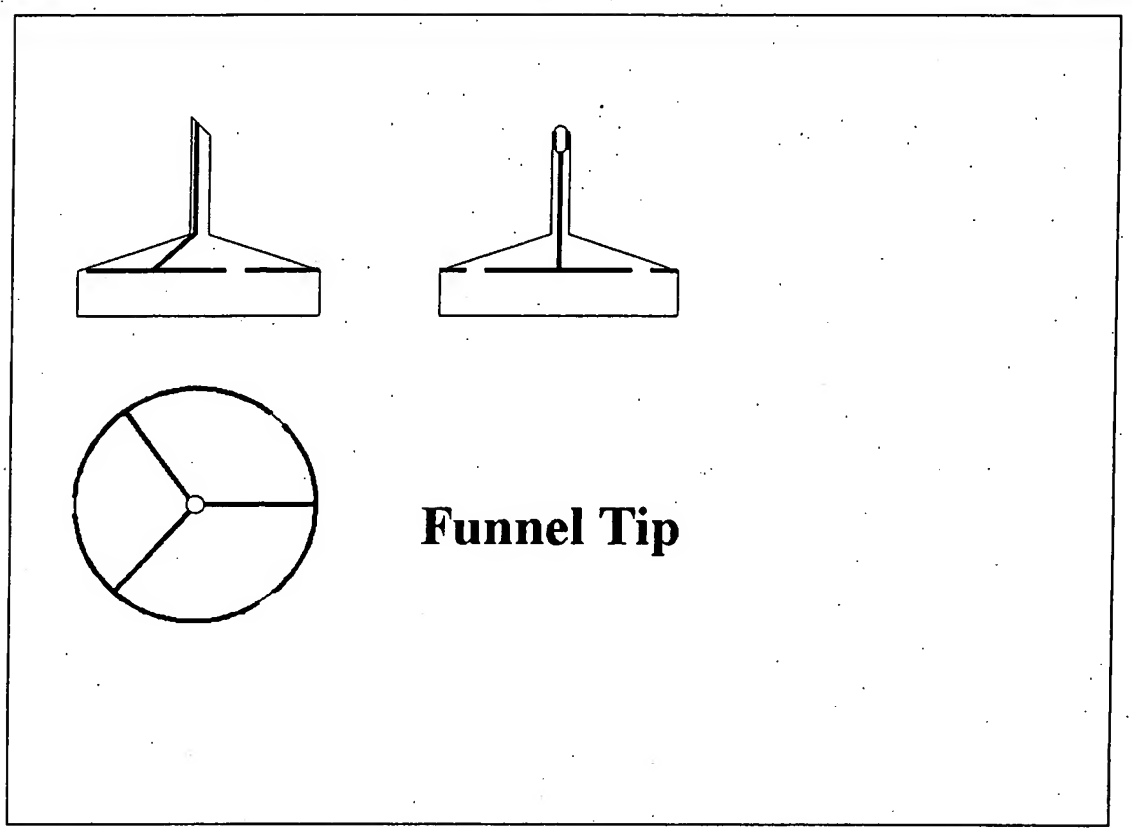
DESCRIPTIVE TITLE: Trans-Septal Sheath with a Splitting Dilating Needle.

I. **INSTRUCTIONS:** This form should be typed, except for the signatures and dates. Disclose only one invention on this Invention Disclosure form, and complete the entire form as fully as possible. Forward the completed form to the Legal Department, signed and dated by all inventors and two witnesses. Refer to this Invention Disclosure by the number assigned to it when receipt is acknowledged. Attach additional sheets if more space is required. Each original piece of paper must be signed and dated by every inventor and by each witness.

II. **ILLUSTRATION:** *Include a drawing, sketch, photograph, flow chart, or preferably an engineering quality printout of the invention.*



[redacted] [redacted] Y. Keith [redacted]



III. **EXPLANATION OF INVENTION:**

Background: Atrial fibrillation and other arrhythmia in the left atrium require catheter access for mapping and ablation in the left atrium. One approach used today to gain access to the left atrium are a trans-septal sheath system that uses a needle, a dilator and a sheath. Using such a system works well, but suffers from a few disadvantages:

1. There are at least three different devices working together which would require numerous exchanges and management of fluids aspiration and pressure monitoring through more then one lure.
2. After the needle puncture, the trans-septal hole is dilated by advancing a tapered-tip-dilator into the left atrium. To dilate the hole enough for the sheath to fit in the dilator with the sharp needle has to be advanced ten to twenty millimeters into the left atrium which would bring the sharp edge dangerously close to the superior wall of the left atrium and might result in perforation, especially if the left atrium is small. Most needle and dilator systems have no safety mechanism to stop the device from being advanced too far into the left atrium.
3. When the sheath is advanced into the left atrium it is typically placed at least 10 mm into beyond the septum wall. If it is advanced less than that it might fall out of the left atrium. This gives catheter or devices that go through this sheath very limited access to the septum from the left side. If the procedure requires mapping or ablation on the left septum it is almost impossible to do with conventional sheaths.

[redacted] [redacted] [redacted]

Invention: The disclosed device is a trans-septal sheath with an apparatus on the distal tip, which is like a Nitanol funnel that ends with a sharp needle. The funnel has laser-cut slots that divide it into three or more segments. After puncturing the septum, the funnel can be pulled back over the distal end of the shaft splitting it open, dilating the trans-septal hole, and anchoring the sheath in the left atrium, flat of the septal wall. The funnel is pulled back over the shaft using wires, and can be locked in the open position by a latch. The sheath has a valve to introduce catheters and device through, and a side port for fluid management and pressure monitoring.

IV. **NOVEL FEATURES AND ADVANTAGES:**

1. No need for needle or dilator.
2. No need to change the pressure monitoring from the needle to the sheath.
3. The shape of the tip prevents over extending the needle and acts as a backstop.
4. The mechanism dilates the hole without advancing the needle or sheath.
5. The Nitanol has shape memory that allows the gaps in the slots to acts as hinges as well as springs. When released the tip would resume its original closed shape.
6. The latch locks the tip in the open position, anchoring the sheath in the left atrium, flat on the septum.

V. **MODIFICATIONS**

- Different number of segments in the tip
- Materials other than Nitanol
- Combination of this device and a guide wire to protect from trauma from the sharp tip when introducing and retracting the sheath from the patient body
- Side holes

VI. **RELATED DOCUMENTS:** *List all known relevant art references (patents, publications, commercially available products, etc.)* Please supply copies of the documents, if available.

Patents:

Publications:

Signature of Inventor(s): Date: Witnesses: Date:

[redacted]

[redacted]

VII. **INVENTORS:**

First Inventor's Full name (Please type:) Yaron Keidar

Signature: Y. Keidar Date: [redacted]

Second Inventor's Full Name (Please type):

Signature: _____ Date: _____

VIII. **WITNESSES:** This invention was disclosed to and understood by:

Full Name of First Witness (Please type):

Signature: Kristine Fujimoto Date: [redacted]

Full Name of Second Witness (Please type:)

Signature: Pete Klumb Date: [redacted]

IX. **ADDITIONAL INFORMATION:**

Invention is recorded on page(s): _____ of Notebook No.: _____ dated: _____

Earliest date: _____ and place: _____ where inventors first thought of the present invention.

First written description (date and present location): _____

First sketch of the invention (date and present location): _____

Earliest date: _____ and place: _____ where first operating model was completed.

Present location of model: _____

Earliest date of use of the invention (actual or contemplated): _____

Earliest shipping date (actual or contemplated): _____